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| APPLICATION NO.  | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.       | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------------|------------------|
| 10/517,510   | 12/10/2004  | Diane Marie Harvey   | 21023P                    | 9955             |
| 210 7590 01/18/2007<br>MERCK AND CO., INC<br>P O BOX 2000<br>RAHWAY, NJ 07065-0907 |             |                      | EXAMINER<br>AEDER, SEAN E |                  |
|  |             |                      | ART UNIT                  | PAPER NUMBER     |
|  |             |                      | 1642                      |                  |
| SHORTENED STATUTORY PERIOD OF RESPONSE   |             | MAIL DATE            | DELIVERY MODE             |                  |
| 31 DAYS  |             | 01/18/2007           | PAPER                     |                  |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

# Office Action Summary

Application No.

10/517,510

Applicant(s)

HARVEY ET AL.

Examiner

Sean E. Aeder, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 10 December 2004.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1 and 3-19 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1 and 3-19 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

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**DETAILED ACTION**  
***Election/Restrictions***

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1, 3, 4, 18, and 19, drawn to a purified polypeptide comprising an amino acid sequence as set-forth in SEQ ID NO:2 or an amino acid sequence comprising residues 1 to 340 of SEQ ID NO:2.

Group II, claim(s) 5, drawn to a method for screening a compound for effectiveness as an agonist of the polypeptide of group I.

Group III, claim(s) 6, drawn to a method for screening a compound for effectiveness as an antagonist of the polypeptide of group II.

Group IV, claim(s) 7, 8, and 11-14, drawn to polynucleotides encoding the polypeptides of group I.

Group V, claim(s) 9-10, drawn to a method of detecting the nucleic acid molecules of group IV.

Group VI, claim(s) 15, drawn to a method comprising administering a polypeptide of group I.

Group VII, claim(s) 16, drawn to a method of administering a polynucleotide of group IV.

Group VIII, claim(s) 17, drawn to a method of detecting the polypeptide of group I.

The inventions listed as groups I-VIII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The technical feature linking groups I-VIII appears to be that they all relate to the special technical feature of a purified polypeptide comprising an amino acid sequence as set-forth in SEQ ID NO:2 or an amino acid sequence comprising residues 1 to 340 of SEQ ID NO:2.

However, Tang et al (US Patent 6,569,662; filed 7/19/00) teaches a purified polypeptide comprising an amino acid sequence as set-forth in SEQ ID NO:2 or an amino acid

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sequence comprising residues 1 to 340 of SEQ ID NO:2 (see attached sequence comparison).

Therefore, the technical feature linking the inventions of groups I-VIII does not constitute a special technical feature as defined by PCT Rule 13.2, as it does not define a contribution over the prior art.

Accordingly, groups I-VIII are not so linked by the same or a corresponding special technical feature as to form a single general inventive concept.

The inventions of groups I and IV represent separate and distinct products which are made by materially different methods, and are used in materially different methods which have different modes of operation, different functions and different effects.

The DNA of group IV is related to the protein of group I by virtue of the fact that the DNA codes for the protein. The DNA molecule has utility for the recombinant production of the protein in a host cell. Although the DNA and the protein are related, since the DNA encodes the specifically claimed protein, they are distinct inventions because the protein product can be made by other and materially distinct processes, such as purification from the natural source. Further, DNA can be used for processes other than the production of protein, such as nucleic acid hybridization assays. The inventions of groups I and IV have a separate status in the art. In cases such as this one where descriptive sequence information is provided, the sequences are searched in appropriate database.

The inventions of groups II, III, and V-VIII are materially distinct methods which differ at least in objectives, method steps, reagents and/or dosages and/or schedules used, response variables, and criteria for success. Each group would require different searches in the literature, in part, due to the different classifications of each group. Searching all the methods would be unduly burdensome because each search would require different searches in the literature that would not necessarily be co-extensive. Further, examining each method requires the consideration of different patentability issues.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sean E. Aeder, Ph.D. whose telephone number is 571-272-8787. The examiner can normally be reached on M-F: 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shanon Foley can be reached on 571-272-0898. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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